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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,899	01/21/2004	Robert Allan Phillips	14450.0006US01	4223

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EXAMINER	
LEE, YUN HAENG NMN	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
12/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,899	PHILLIPS, ROBERT ALLAN	
	Examiner	Art Unit	
	YUN HAENG LEE	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,9 and 11-14* is/are pending in the application.

4a) Of the above claim(s) *12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 7, 9 and 11, drawn to a method of determining the cardiac output of a patient, classified in class 600, subclass 508.

II. Claims 12-14, drawn to an apparatus for measuring the diameter of the pulmonary valve of a patient, classified in class 600, subclass 508.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Newly submitted claims 12-14 are directed to an invention that is independent or distinct from the invention originally claimed for the above reasons.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nidorf et al. (J Am Coll Cardiol 1992;19:983-8).

Regarding claim 1, Nidorf et al. disclose a method of determining the diameter of a heart valve of a patient, the method comprising the step of calculating, using a single variable formula, the diameter of the heart valve of the patient wherein the single variable is the patient's height (see Table 1). Nidorf et al. further teach that height offers a simple yet accurate means of assessing the normalcy of cardiac dimensions (last sentence of abstract). Since pulmonary annular diameter is also a cardiac dimension, it would be obvious to infer that pulmonary annular diameter would also be predicted by a patient's height. Therefore, it would have been obvious to follow the method of Nidorf et al. to find and use a single variable formula, similar to those in Table 1, to calculate the diameter of the pulmonary valve of a patient wherein the single variable is the patient's height.

Regarding claim 11, Nidorf et al. further discloses using correlation data for the cardiac dimensions of the patient based on the patient's height (Figure 3(C)) in order to obtain the single variable formulas in Table 1 using linear regression. Therefore, a pulmonary annulus version of the formula, as discussed above, would be responsive to correlation data for the diameter of the pulmonary valve of the patient based on the patient's height. Such correlation data would also be indicative of correlation between the patient's height and the diameter of the aortic valve for a population of individuals to the extent that both show a linear relationship between cardiac dimensions and height.

Regarding claims 2 and 3, in addition to the above discussion, see the Methods section of Nidorf et al.

Regarding claim 7, the claimed formula could be derived through routine experimentation using the method of Nidorf et al. as discussed above.

7. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pat. No. 6,565,513) in view of Nidorf et al. (J Am Coll Cardiol 1992;19:983-8). Phillips discloses a method of determining the cardiac output (col. 3 lines 1-2) from the pulmonary annular (col. 2 line 67). As discussed above, it would have been obvious to one of ordinary skill in the art to obtain the pulmonary annular using the method taught by Nidorf et al.

Response to Arguments

8. Applicant's arguments filed 10/7/08 have been fully considered but they are not persuasive. Applicant argues that Nidorf does not extend to the right side of the heart, because it is difficult to directly measure the diameter of the pulmonary valve, even when using advanced echocardiography techniques, unlike the aortic valve. Applicant's statement is clearly false as Phillips (US Pat. No. 6,565,613) appears to have no difficulty obtaining the pulmonary artery diameter (col. 2 line 67). See also Foale et al. (Br Heart J. 1986 Jul;56(1):33-44). Applicant further argues that Nidorf's work cannot automatically be applied to the right side of the heart. Examiner reads Nidorf et al. as

broadly teaching that height offers a simply yet accurate means of assessing the normalcy of cardiac dimensions. Absent any particular evidence why the right side of the heart would not follow such nomalcy of cardiac dimensions, Examiner does not find it unreasonable to apply Nidorf's work to the right side of the heart.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUN HAENG LEE whose telephone number is (571)272-2847. The examiner can normally be reached on M-Th 10-8.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

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